

OS



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
INTER/INTRA-AGENCY AGREEMENT (IAA)
Payable Agreements (CDC is Procuring Agency)



1. CDC IAA #: (10 to 13 digits) 00FED05404-22	2. PARTICIPATING AGENCY IAA #: CPSC-1AG-00-1157	3. TYPE OF AGREEMENT <input type="checkbox"/> New <input checked="" type="checkbox"/> Modification <input type="checkbox"/> Administrative Modification Number: 22					
4. TITLE OF PROJECT: Adverse Effects Due to Therapeutic Drugs							
5. DESCRIPTION OF WORK: (Please attach) See Attached Statement of Work		6. AMOUNT: (Not to exceed without written modification) \$ 102,000.00					
7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY: Consumer Product Safety Commission 4330 East West Highway, Rm 517 Bethesda, MD 20814-4408 DUNS# 178771713		LIAISON NAME: Terri Nelson PHONE #: (301) 504-7509 EMAIL ADDRESS: tnelson@cpsc.gov FAX #: (800) 809-0924					
8. NAME AND ADDRESS OF CDC, CENTER, INSTITUTE OR OFFICE: National Center for Injury Prevention and Control Division of Injury and Disability Outcomes and Programs 4770 Buford Highway, NE Mailstop F-41 Atlanta, GA 30341 DUNS# 927645465		LIAISON NAME: Dan Budnitz, M.D. PHONE #: (770) 488-1486 EMAIL ADDRESS: DBudnitz@cdc.gov FAX #: (770) 488-4338					
9. PROJECT PERIOD: from: 10/01/2004 through: 09/30/2005		FUNDING PERIOD: from: 10/01/2004 through: 09/30/2005					
10. CDC AUTHORITY: <input checked="" type="checkbox"/> Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535 and 1536 (See also item #14) <input type="checkbox"/> Other (Please specify) _____							
11. PARTICIPATING AGENCY AUTHORITY: Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act							
12. CDC FUNDING INFORMATION: FOR CDC USE ONLY (CDC Internal form 6012 - modified Document History Record)		APPROPRIATION NUMBER: 7530043 7550943					
T.C. (For Accounting Use Only)	FY (2 digits) (Required)	DOC. REF. (For Accounting Use Only)	DOC. NO. (Original 10 digits) (Required)	CAN (7 digits) (Required)	O.C. (4 digits) (Required)	ALLOWANCE (5 digits) (For Budget Use Only)	\$ AMOUNT
050	05	214	00FED05404	9211995	253R	19467-03	\$68,000.00
050	05	214	00FED05404	921HQ46	253R	19116-08	\$34,000.00
				↑ UFMS = 25330			
6012 ADMINISTRATIVE APPROVAL NAME and EMAIL ADDRESS: (Please print) Margaret Brome Acting Deputy Director, DiDOP, NCIPC MBrome@cdc.gov						FMO BUDGET ANALYST SIGNATURE: ADMINISTRATIVE APPROVAL SIGNATURE: Margaret Brome	
(Should not be the same as Block #18)							



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13. ADMINISTRATIVE BILLING REQUIREMENTS: CDC's ALC is **75090421**. Other Agency's ALC: *(required)* 61000001

Billing is to be made through the use of the Online Payment and Collection (OPAC) system. Please include CDC's Official IAA # from Block #1 on all OPAC billings and correspondence. When CDC provides funds to the performing agency, in advance of receiving the goods or services, the performing agency agrees to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. The statements shall be provided to the following address: DHHS, CDC, FMO, AP, Attn: ADVANCES/OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333. (If required by other agency, CDC's Tax Identification # is 586051157.)

14. ADDITIONAL BILLING REQUIREMENTS: *(This block must be completed if procuring services under the Economy Act.)*

- ☒ All funds provided by CDC under this agreement must be obligated by the performing agency by the end of the FY in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the FY so that the agreement may be modified to reduce the funding amount when appropriate. This notification shall be provided to the following address:
DHHS, CDC, FMO, AP, Attn: OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333.

15. PARTICIPATING AGENCY FUNDING and/or INFORMATION:

(Please include name, telephone number, and email address of contact person.)

Name:	Telephone #:	Email:
Deborah Hodge	(301) 504-7130	dhodge@cpsc.gov

16. ☒ The participating agency as a signatory to the Common Rule states that in accepting these Interagency Agreement funds, it will abide by the human subjects research requirements stated in the Common Rule, and certify that all necessary assurances and institutional review board (IRB) approvals are obtained.

☐ The participating agency is NOT a signatory to the Common Rule. Upon issuance of these Interagency Agreement funds, it is the responsibility of the CDC Center, Institute, or Office (CIO) to certify that all necessary assurances and institutional review board (IRB) approvals are obtained. The CIO Associate Director for Science (ADS) must determine the Applicability of Human Subjects Regulations.

17. OTHER REQUIREMENTS:

A. Travel under this agreement is subject to allowances authorized in accordance with Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.

B. CDC will retain the title to any equipment procured under this agreement, unless otherwise justified in the statement of work.

18. CDC ACCEPTANCE: *(please print)*

Name: Illeana Arias

Title: Acting Director, NCIPC

Email address: lArias@cdc.gov

Signature: *Deborah Hodge*

Date: 4/29/05

19. PARTICIPATING AGENCY ACCEPTANCE: *(please print)*

Name: Donna Hutton

Title: Contracting Officer

Email address: dhutton@cpsc.gov

Signature: *Donna Hutton*

Date: 5/11/05

This agreement may be terminated by either agency upon a 30-day advance written notice. This agreement may be modified by mutual written consent of all parties.

**STATEMENT OF WORK
INTERAGENCY AGREEMENT (IAA)
BETWEEN
THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
AND
THE U.S. CONSUMER PRODUCT SAFETY COMMISSION (CPSC)**

This document sets forth the terms of agreement for services, supplies, and/or material between the U.S. Consumer Product Safety Commission (CPSC) and the Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC).

This document serves as an addendum to the Interagency Agreement (00FED05404) between the Centers for Disease Control and Prevention and the U.S. Consumer Product Safety Commission covering the expansion of the National Electronic Injury Surveillance System (NEISS) to collect data on all injuries.

This addendum covers a special study entitled: "Adverse Events due to Therapeutic Drugs (ADEs)" which is outlined below.

I. DESCRIPTION OF SERVICES

A. Background

Adverse events due to therapeutic drugs (ADEs) may be responsible for over 100,000 deaths a year, which would make ADEs the 5th leading cause of death in the United States (JAMA 1998;279:1200-5, 1216-7). Several large studies have focused on ADEs in the hospital setting. In the outpatient setting, however, we know relatively little about adverse drug events. The National Electronic Injury Surveillance System – All Injury Program (NEISS) can play an important role in collecting information about outpatient ADEs.

In FY02, a pilot study in which 10 NEISS hospital coders were trained to collect data on ADEs for 10 weeks demonstrated the feasibility of training NEISS hospital coders to collect data on ADEs. Findings from this demonstration of feasibility were published in the Annals of Emergency Medicine, 2005;45(2):197-206.

In FY03, based on the results of the pilot study, the Food and Drug Administration (FDA) and CDC collaborated to improve the data collection instrument and coder training that was used in the pilot study. CPSC has incorporated the improved data collection instrument ("second screen") into the computerized data collection system used in NEISS. All NEISS-AIP hospital coders were trained to identify and report information on patients with ADEs by receiving formal training as part of a July training conference or a distance-based education module and completed practice exercises and an evaluation exercise. Data collection using the computerized data instrument began August 1, 2003 and CPSC delivered that data to CDC on a monthly basis for the last two months of FY03.

In FY04, data collection continued on a regular basis using a computerized "second screen." Preliminary data from ADE cases was provided to CDC on a monthly basis in the form of SAS datasets. Final data was provided to FDA and CDC annually. CDC and CPSC representatives collaborated to conduct a formal evaluation of ADE data collection in a subset of NEISS-AIP hospitals. Results of this evaluation are to be published in the Morbidity and Mortality Weekly Reports in the Spring of 2005. A training update was provided for hospital coders via distance-based instruction or a summer training conference.

B. Purpose

To continue Adverse Drug Event data collection, reporting, and quality control procedures in FY05. Data collection using the computerized instrument will continue in all NEISS-AIP hospitals as has been done in FY04. Preliminary data from ADE cases will be provided to CDC on a monthly basis in the form of SAS datasets. Final data will be provided to FDA and CDC yearly. CDC and/or FDA representatives will continue to collaborate with CPSC representatives to provide continuous quality evaluation and training updates for coders via distance-based instruction and/or a summer training conference. Both parties in good faith intend to continue the funding and data collection outlined in this agreement in FY06.

C. Overview of Methods

1. Data Collection: Data collection using the computerized instrument used in FY04 will continue in FY05. CPSC will manage the collection of data in this instrument as it manages other data reported in NEISS-AIP.
2. Data Delivery: Preliminary data from ADE cases will be provided to CDC on a monthly basis in the form of SAS datasets. Finalized data will be provided to FDA and CDC yearly. CPSC will also provide data and statistical support so that population-based estimates, time trends, and comparative estimates may be calculated.
3. Quality Assurance: Data entered in the ADE instrument will be quality reviewed in the manner of other data entered in NEISS-AIP. Using preliminary data reported monthly and periodic hospital site visits, CDC, FDA, and CPSC will collaborate on evaluation and continuous quality improvement for case ascertainment and data accuracy.
4. Continuous Quality Improvement: CDC and/or FDA representatives will continue to collaborate with CPSC representatives to provide continuous quality evaluation and "refresher" training for coders via site visits and/or distance-based instruction.

II. EQUIPMENT

There is no equipment to be covered under this agreement.

III. ESTIMATED COSTS

The estimated cost of the NEISS Special Study of Adverse Drug Events for FY'05 is \$102,000. The breakdown in cost is as follows:

CPSC Charges

1. ADE Case reporting and quality assurance 18,000 cases per year x \$4 each case	\$72,000
2. Administrative costs for programming support, delivering data, improving quality assurance, and evaluation activities	\$30,000
<u>TOTAL</u>	<u>\$102,000</u>

IV. PROGRAM CONTACTS

CDC: Jacqui Butler
Public Health Analyst
DIDOP/NCIPC, MS-F-41
4770 Buford Highway, NE
Atlanta, GA 30341-3724
(770) 488-1496

CPSC: Terri Nelson
Program Analyst
EPDS Rm.604-36
4330 East-West Highway
Bethesda, MD 20814-4408
(301) 504-7509

V. CPSC ACCOUNTING DATA

05 PS EXOB 4310 11179 252e
DUNS: 069287522
TIN: 520978750
ALC: 61-00-0001
US Treas. Code: 6150100